EVALUATION OF EFFECTIVENESS OF VARNISH CONTAINING FLUORIDE AND FLUORIDE VARNISH WITH CPP-ACP IN PREVENTION OF WHITE SPOT LESIONS IN PATIENTS UNDERGOING FIXED ORTHODONTIC THERAPY - AN INVIVO COMPARATIVE STUDY

A Dissertation submitted
in partial fulfilment of the requirements
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ORTHODONTICS & DENTOFACIAL ORTHOPEDICS

CERTIFICATE

This is to certify that DR N.KARIKALAN, Post graduate student (2015-2018) in the Department of Orthodontics and Dentofacial Orthopedics, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319, has done this dissertation titled **"EVALUATION OF EFFECTIVENESS OF VARNISH CONTAINING FLUORIDE AND FLUORIDE VARNISH WITH CPP-ACP IN PREVENTION OF WHITE SPOT LESIONS IN PATIENTS UNDERGOING FIXED ORTHODONTIC THERAPY - AN INVIVO COMPARATIVE STUDY"** under our direct guidance and supervision in partial fulfillment of the regulations laid down by The Tamilnadu Dr .M.G.R Medical University, Chennai – 600032 for MDS; (Branch V) Department of Orthodontics& dentofacial Orthopedics Degree Examination.

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DECLARATION

TITLE OF THE DISSERTATION	"**Evaluation of effectiveness of varnish containing fluoride and fluoride varnish with CPP-ACP in prevention of white spot lesions in patients undergoing fixed orthodontic therapy - an invivo comparative study"**
PLACE OF THE STUDY	Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319
DURATION OF THE COURSE	3 years
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I hereby declare that no part of the dissertation will be utilized for gaining financial assistance or any promotion without obtaining prior permission of the Principal, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319. In addition, I declare that no part of this work will be published either in print or in electronic media without the guides who has been actively involved in dissertation. The author has the right to reserve for publish work solely with the permission of the Principal, Adhiparasakthi Dental College and Hospital, Melmaruvathur – 603319

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ABSTRACT

AIM:

The aim of the study is to compare the in vivo efficiency of MI varnish containing casein phosphopeptide (CPP) and amorphous calcium phosphate (ACP) and Fluoritop containing sodium fluoride (5% NaF) in prevention and remineralisation of white spot lesions around orthodontic brackets at 28th and 56th day after bonding.

MATERIALS AND METHODS:

30 patients were selectede and divided into 2 groups I (MI Varnish) & II (Fluoritop varnish) of 15 patients in each group. All the Patients were bonded and then varnish was applied around the brackets. Right side uper and lower first premolar were taken as control group and left side uper and lower first premolar as experimental group. 14,24 teeth were extracted on 28th day after bonding and 34,44 teeth after 56th day of bonding. Samples were collected and sent to laboratory for evaluation of surface micro hardness (SMH).

RESULTS:

Based on the statistics results, there was significant decrease in demineralisation and increase in remineralisation of white spot lesion (WSL) after the application of varnish. No statistical significance was found between effectiveness of MI varnish and fluoritop except in cervical region.

CONCLUSION:

By our study we concluded that no statistical significance was found between effectiveness of MI varnish and fluoritop except in cervical region where MI varnish was found to be more effective than fluoritop in preventing WSLs.

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LIST OF ABBREVIATIONS

WSLs	**-**	**White spot lesions**
APDC&H	**-**	**Adhiparasakthi Dental College & Hospital**
CCP-ACP	**-**	**Casein Phosphopeptide – Amorphous Calcium Phosphate**
SMH	**-**	**Surface Micro Hardness**
VHN	**-**	**Vickers Hardness Number**
NaF	**-**	**Sodium Fluoride**
&	**-**	**and**

INTRODUCTION

White spot lesions (WSLs) are opaque white areas caused by the loss of minerals below the outermost enamel layer. WSLs are common and an unfavourable sequelae of the orthodontic treatment which in turn compromise esthetics and can be extremely difficult to reverse[1].

Fixed orthodontic appliances attributes to the development of white spot lesions (WSLs) in number of ways by making conventional oral hygiene procedures more difficult for the patients, by increasing the number of plaque retention sites on the less caries susceptible surfaces of the teeth and by prolonging plaque accumulation around the brackets [2,3,4,5,6,7] .

The main mechanism of WSLs formation around orthodontic appliances are by rapid increase in acidogenic bacterial flora of plaque mainly Streptococcus Mutans and Lactobacilli [8]. Acidogenic bacterial flora decrease the pH of the plaque in orthodontic patients to a greater extent than in non-orthodontic patients. Therefore the progression of caries is faster in patients with full orthodontic appliances[9].

WSLs can become noticeable around the fixed appliances within 1 month of bracket placement, usually it takes at least 6 months duration for the formation of regular caries. The buccal surfaces of the teeth around the brackets, especially in the gingival region are more vulnerable for WSLs[10,11].

Saliva is capable of slowly remineralising WSLs to some degree, but complete resolution of the lesions occurs very rarely[12,13]. The pattern of remineralization follows a time trend, with greater remineralization during the first few months and then continuing at a slower rate[14,15].

Although prevention of WSL is an important goal for every orthodontist, the prevalence of WSLs after orthodontic treatment has been reported to be 5% to 97% [2].

Fluoride plays a vital role in the prevention of enamel demineralization. Fluoride has been shown to increase the initial rate of remineralization[6].

For over period of years several researches have been conducted to prevent demineralisation and induce remineralisation with the help of fluoride application.

There are several methods of delivering fluoride to the teeth in patients undergoing orthodontic treatment. These include topical fluorides (e.g. mouthrinse, gel, varnish, toothpaste) and fluoride-releasing materials (e.g. bonding materials, elastics) [16].

High doses of fluoride during and after orthodontic treatment for arresting decalcification causes an increase in remineralization of the outer enamel and a decrease in demineralization of the inner enamel, resulting in a significant mineral gain[17]. However contradictory opinions were also prevalent against the use of high concentrations of

fluoride that it will cause remineralization mainly in the superficial part of the WSLs[18,19]. This superficial layer might prevent calcium and phosphate from penetrating to the deeper layers of the enamel, thus inhibiting deeper remineralization and limiting the cosmetic improvement of the WSLs. Thus, the most ideal concentrations and delivery vehicles for fluoride remain controversial.

The active agent, casein phosphopeptide-amorphous calcium phosphate is thought to stabilize and localize calcium, fluoride, and phosphate at the tooth surface in a slow-release amorphous form, thus enhancing deeper layer remineralization of WSLs[20.]

Few in-vivo studies had investigated the effectiveness of remineralization products to address the problem of WSLs formation during and after orthodontic treatment. With that in mind, this study was conducted as randomized clinical trial on 2 commercially available products, 'MI Varnish' [5% sodium fluoride varnish with Recaldent (CPP–ACP), GC America, USA] and 'Fluoritop SR' [5% sodium fluoride varnish, ICPA Health Products Limited, India] to assess their clinical effectiveness in preventing demineralization & promoting remineralization around bracket surfaces at 28th day and 56th day after bonding.

AIM AND OBJECTIVES

AIM OF THE STUDY

The aim of the study is to compare the in vivo efficiency of MI varnish containing casein phosphopeptide (CPP) and amorphous calcium phosphate (ACP) and Fluoritop containing sodium fluoride (5% NaF) in prevention and remineralisation of white spot lesions around orthodontic brackets at 28^{th} and 56^{th} day after bonding.

OBJECTIVES

- To determine the effectiveness of MI varnish containing CPP and ACP in Preventing WSL after 28 days and 56 days in patients undergoing fixed orthodontic therapy.
- To determine the effectiveness of Fluoritop varnish containing sodium fluoride in preventing of WSL after 28 days and 56 days in patients undergoing fixed orthodontic therapy.
- To compare the effectiveness between MI varnish and Fluoritop in preventing WSLs.
- To design a standard protocol for the quantification of decalcification, prevention and management of WSLs.

REVIEW OF LITERATURE

Stratemann et al [21] (1974) evaluated the incidence of decalcification in orthodontic patients and effectiveness of the daily use of a 0.4 percent stannous fluoride gel in the reduction of mineral loss from enamel on 209 patients with banded teeth and found incidence of decalcification in the control group was 58 percent. Decalcification was found in only 2 percent of the fifty-one patients who used the gel as directed on a daily basis.

DO.Hughes et al[22] (1979) conducted an in-vitro study to evaluate the effectiveness of several polymeric adhesive coating and resinous coating materials used for the prevention of decalcification of the enamel teeth surface on 120 extracted premolar teeth by visual perception. The result showed that the teeth treated by acid etched material were proved to be effective over a period of 21 weeks. Between acid etched materials, unfilled BIS-GMA is proved to be significantly more effective in protecting against decalcification.

Mizrahi et al[23] (1982) carried out a cross-sectional study to determine the prevalence and severity of enamel opacities in patients before and after orthodontic treatment in 527 patients prior and 269 patients examined after completion of multi banded orthodontic treatment. There was a significant increase in the severity of enamel opacities following orthodontic treatment. There was no significant sex differential in the prevalence of enamel opacities either before or after the orthodontic treatment. This study

showed that orthodontic treatment with multi banded appliances contributed to the development of new areas of enamel demineralization and increase in the severity of enamel opacities.

Mizrahi et al [24] (1983) did a cross-sectional study to determine the prevalence and severity of enamel opacities on 527 patients examined prior and 269 after completion of multibanded orthodontic treatment. The results showed that following orthodontic treatment there was a significant increase in the prevalence of enamel opacities on the vestibular and lingual surfaces of the dentition. The increase was significantly greater on the cervical and middle thirds of the crown. Among individual teeth, there was a statistically significant increase in the prevalence and severity of enamel opacities on the maxillary and mandibular first molars, the maxillary lateral incisors, and the mandibular lateral incisors and canines. The increase was more on the cervical and middle thirds of the vestibular surface of these teeth.

Leonard Gorelick et al [2] (1982) did a retrospective study to rule out the incidence and severity of white spot lesion around teeth that are banded and bonded. They did direct examination for both bonded teeth and for canine to canine retainers whereas indirect slide examination for the banded teeth .Indirect clinical examination was done with kodachrome slides before and after treatment. The results showed the labio gingival area of the maxillary lateral incisors has the highest incidence and were lowest in maxillary

posterior segment. No white spots were found on the lingual surface of mandibular teeth. Author concluded the need of preventive programs to reduce the degree of iatrogenic damage during orthodontic treatment

Leonard Gorelick, Arnold M. Geiger et al [25] (1988) did a clinical study on preventive fluoride program. The observations made from the clinical study are 1. Decalcification of labial surfaces of teeth during orthodontic therapy can be significantly reduced by consistent use of 0.05% sodium fluoride rinse during treatment. 2. The incidence and severity of white spots formation are related to the length of time teeth are bracketed. 3. The one time topical application of acidulated phosphate fluoride gel immediately after bonding appears to be of little benefit in reducing the incidence of white spots.

Ogaard etal[10] (1988) conducted a clinical trial to investigate carious lesion development associated with fixed orthodontic therapy and concluded that demineralization is an extremely rapid process caused by a high and continuous cariogenic challenge in the plaque developed around brackets and underneath ill-fitting bands. On absence of fluoride application white spot lesions were seen within 4 weeks.

O'Reilly et al[26] (1987) did a study to determine the amount of demineralization and the ability of various fluoride products to inhibit or reverse orthodontically related demineralization on 20

patients who were given precise oral hygiene instructions and used sodium fluoride dentrifrice .In this study there was measurable demineralization occurred around orthodontic appliances after only 1 month and this demineralization can be completely inhibited and or reversed by the use of fluorides.

B.Ogaard et al[19](1988) did a clinical study in a group of children aged 11-14 years, in whom premolars were to be removed for therapeutic extraction to investigate the effect of fluoride on caries lesion development and on lesions established during fixed orthodontic therapy. The results showed that daily rinse with 0.2% solution of sodium fluoride retarded lesion development significantly whereas fluoride solution with low PH inhibited lesion formation completely. The remineralizing capacity of saliva was found to be rapid in the absence of fluoride. Visible white spot lesion should not be treated with high concentration of fluoride which arrest the lesion and prevents complete repair.

Ogaard et al[6] (1989) evaluated the prevalence of white spot lesions on the vestibular surfaces of 19 year olds subjected to and not subjected to orthodontic treatment. The median white spot score was significantly higher in the orthodontic group than in the untreated group. The highest prevalence was on the first molars in both groups. In the orthodontic group the mandibular canines and premolars and the maxillary lateral incisors were also affected. The study concluded that white spot lesions after orthodontic treatment

with fixed appliances acts as an esthetic problem, even more than 5 years after treatment

Arnold M. Geiger et al[27] (1992) conducted a clinical study to determine the white spot lesion with daily rinse of neutral 0.05% sodium fluoride before bedtime. Rinsing was done after brushing with fluoridated paste. Visual inspection concluded that a significant reduction in enamel white spot lesions can be achieved during orthodontic therapy by the use of a 0.05% neutral sodium fluoride rinse.

Bjorn Ogaard et al[28](1992)conducted a in vivo study to investigate the cariostatic potential of a non fluoride adhesive (Heliosit-orthodontic) and a fluoride containing adhesive(Orthodontic cement VP 862) on premolars to be extracted after 4 weeks Micro radiography was used to determine the mineral content. The fluoride release of orthodontic cement in water and saliva was observed. They concluded that the regular use of fluoride tooth paste is insufficient to inhibit lesion development. The fluoride releasing adhesive reduced lesion development significantly.

P.A.Banks et al[29] (1994) conducted a clinical trial to evaluate the effectiveness of viscous chemically cured bonding agent (Maximum cure) and nonviscous visible light cure bonding agent (Trans bond resin) in the prevention of enamel decalcification following bracket bonding. Enamel decalcification index was used to assess the decalcification. Scores were obtained by direct clinical observation.

The results showed that 75% of patients were affected by some decalcification. The viscous sealant reduced the extent of decalcification of tooth zones by 13% and the non -viscous sealant produced no significant difference. They concluded that further research is needed to develop a material which provides greater enamel protection.

Ullsfoss et al[30] (1994) evaluated the caries inhibitory effect of combining 0.2 percent Chlorhexidine (CHX) mouthrinses used twice daily with single daily use of 0.05 percent sodium fluoride rinse in human caries model using plaque-retaining bands on premolars, analyzed by micro radiography The combination of CHX and Fluoride rinses resulted in slight mineral loss in enamel but higher than that observed in sound enamel and clearly less than with Fluoride rinses alone plaque bacteria and Streptococcus Mutans were reduced by CHX rinses, confirming the discrete mechanisms of action.

Linton et al [31] (1996) did an in vivo study to evaluate white spots and remineralisation of carious lesions and also compared the effect of different levels of both experimental and commercial fluoride solutions on the remineralisation of enamel carious lesions on extracted human teeth using clinical photography which were recorded in 35mm clinical camera. Using microradiograph testing, and the actual mineral contents were calculated. They found that clinical photography is not an adequate method of monitoring the remineralization

L.M. Trimpeneers et al[32] (1996) conducted a clinical trial to compare the effect of a visible light cured fluoride releasing material with a chemically cured non fluoride non-mix resin on white spot formation during fixed orthodontic therapy. Found that that there was no significant difference between the calcification rates for both types of adhesives.

Mark A. Todd et al [33](1999) assessed the ability of fluoride varnish (Duraflor) to inhibit demineralization of enamel surrounding 36 canines and premolars brackets. Group 1 with no topical application, Group 2 with non fluoridated placebo varnish, Group 3 was treated with a single application of Duraflor. Demineralization of enamel was evaluated using polarized light microscopy and average depth and area of demineralization were measured with a sonic digitizer. Those teeth treated with Duraflor exhibited 50% less demineralization.

BjørnØgaard etal [34](2001) concluded in orthodontic patients application of an antimicrobial varnish in combination with a fluoride varnish was significantly more efficient in reducing white spot lesions on the labial surfaces than application of the fluoride varnish alone.

Foley et al[35] (2002) conducted an in vitro study to evaluate the potential of 3 orthodontic cements on enamel demineralisation on one hundred twenty extracted human molars under artificial saliva for 30 days at 37 ^{0}C .The cements used were zinc phosphate cement,

zinc polycarboxylate cement, resin-modified glassionomer (RMGI), then debanded with a customized band-removal device attached to a universal testing machine. subjected to dye (10% methylene blue) for 24 hour ,the depth of dye penetration was determined and used as a measure of the caries preventive effect of the banding cement. The 2 fluoride-releasing cements (zinc polycarboxylate and RMGI) demonstrated less demineralization than the zinc phosphate and provided greater protection from demineralization.

Sigurd Hadler-Olsen et al [36](2005) assessed the effect of a comprehensive prophylactic regimen in reducing the incidence of white spot lesions (WSLs) and caries during orthodontic treatment using WSL index on 80 patients. Twenty-three percent of treated patients showed good compliance, 68 percent moderate compliance, and 9 per cent poor compliance. Orthodontically treated patients had significantly higher risk for developing WSL than untreated patients, while there is no difference with respect to development of new dentinal caries lesions. This study showed the possible relationship between compliance and WSL development.

PE Bensen et al [37](2005): did a study to evaluate the effectiveness of fluoride in preventing white spot lesions. Types of interventions they selected were topical fluoride applications (toothpaste, mouth rinse, gel and varnish) and materials containing fluoride. The review was carried out according to the standard Cochrane systematic review methodology. The databases searched were

Cochrane Clinical Trial Register, MEDLINE, and EMBASE. They reviewed the available data for the presence or absence of WSL by patient at the end of treatment and quantitative assessment of enamel mineral loss or lesion depth. They concluded that some evidence proved the use of a daily 0.05% NaF mouth rinse or a GIC for bonding brackets might reduce the occurrence and severity of WSL during orthodontic treatment. More high quality, clinical trials are required into the different modes of delivering fluoride to the orthodontic patient.

Soliman et al [38] (2006) did a study to measure the rate and amount of fluoride ions released from the sealant over a period of 17 weeks and to determine the fluoride-releasing sealant recharging ability when fluoride ions are reintroduced into the environment. Using an ion analyzer, the fluoride release using a fluoride ion–specific combination electrode is measured and the control sealant showed no significant fluoride release and was unable to absorb the fluoride ions. The fluoride containing sealant Pro Seal released fluoride ions in sustained but significantly decreasing amounts and it had the ability to be recharged with fluoride ions.

Nasrin Farhadian, et al [39] (2008) did an in vivo study to evaluate the short term effect of single-dose application of a high concentration fluoride varnish on enamel decalcification adjacent to bonded brackets in fifteen patients who needed two premolars extraction and concluded that the fluoride varnish can be beneficial

as a preventive adjunct in reducing demineralization adjacent to brackets.

Derrick Willmot et al [40](2008): in his systematic review on "white spot lesion after orthodontic treatment", he found maxillary lateral incisors and mandibular canine teeth are more prone to demineralization. The distogingival area of the labial enamel surface is the most commonly affected. There is an exponential reduction in size of white spot lesion size in first few weeks. Fluoride in high concentration should not be used as treatment as it arrests the remineralisation. White spot lesions left untreated after removal of appliance will naturally reduce in size with no intervention. Casein calcium phosphate materials and salivary stimulation by chewing gum may be effective in assisting remineralisation .For severe cases, acid micro abrasion is recommended.

Bjorn Ogaard et al[41] (2008) Studied the mechanism of white spot lesion formation and fluoride prevention aspects and concluded that decalcifications of the enamel surface are the most important iatrogenic effect caused by fixed orthodontic therapy. The bonded attachments create the retention sites for plaque accumulation. This creates a cariogenic environment where increased levels of S. mutans are observed after starting appliance therapy. Fluorides are found to be most potent inhibitor for decalcification process. There are various fluoride supplements available to inhibit the

development of white spot lesions during the course of time. Patient cooperation with optimal oral hygiene and fluoride supplement is crucial for prevention. Stannous fluoride has a plaque inhibiting effect and interferes with acidogenicity of plaque. Topical fluoride in the form of solutions, varnishes, or gels is found to be feasible and safe methods for fluoride application.

Reynolds et al[42] (2008) did a study to determine the ability of CPP-ACP to increase the incorporation of fluoride into plaque and to promote enamel remineralization using mouthrinses and dentifrices containing CPP-ACP and fluoride. 2% CPP-ACP to the 450 ppm-fluoride mouthrinse significantly increased the incorporation of fluoride and found that dentifrice containing 2% CPP-ACP plus 1100 ppm fluoride was superior to all other formulations.

Christos Livas et al [43] (2008): did a study to find the use of image analysis for diagnosis and quantification of artificial white spot lesions on digital photographs before and after removal of orthodontic brackets. The results showed that image analysis using digital photographs is a reproducible and accurate method. Under controlled light conditions and camera positioning, this method may be a useful tool for early diagnosis of enamel demineralization during orthodontic treatment.

Benson et al[44] (2008) stated that Clinical assessment of WSLs should be simple and inexpensive. But its validity is difficult to distinguish clinical white spots with developmental hypoplasia or

fluorosis. Photographs are the part of patient's clinical records. It can be used for assessment session and re-examined at a different time to determine reproducibility. These photographs are more versatile than a visual examination. Optical non fluorescent methods like light scattering are useful but this is technique sensitive. A laser fluorescence instrument called Diagnodent which was thought to be an indication of bacterial activity, rather than mineral loss. The problem with the QLF is the size of the instrument, which limited the practical use of this technique. The method should be straight forward for the clinician to produce the reliable information regarding the effectiveness of any intervention.

Samir E. Bishara et al [45](2008) concluded the prevalence of white spot lesion due to orthodontic therapy reduced significantly with the daily use of 0.05% NaF. The application of topical fluoride is often considered as the first step in treatment. It is recommended to begin with most conservative approach to resolve the problem of white spot lesion.

Joshua A. Chapman et al [46](2010) did a retrospective study to determine the incidence and severity of white spot lesions at the time of fixed orthodontic appliance removal with routine digital photographs. Results showed the order of incidence of WSL in lateral incisors (34%), canines (31%), premolars (28%), and central incisor. They concluded that the risk factors for the development were young age at the start of treatment, poor hygiene during

treatment, unfavorable clinical outcome score, white ethnic group and inadequate oral hygiene at the initial pretreatment examination.

Behnan et al [47] (2010) did an invitro study to compare potential effectiveness of ACP cement(Aegis-Ortho, Bosworth, Skokie, Ill), resin Transbond XT [3M Unitek, Monrovia, Calif], control, or resin followed by application of fluoride varnish (Vanish, 3M, St Paul, Minn), resin sealer (Pro-seal, Reliance Orthodon-tic Products, Itasca, Ill), or casein phosphopeptide-ACP paste (MI Paste) in prevention of demineralization. The demineralization was assessed by using light-induced fluorescence and confocal laser scanning microscopy and they found both light-cured filled resin (Pro-seal) and fluoride varnish (Vanish) might prevent enamel demineralization.

Leizer et al [48](2010) compared the effect of a fluoride-releasing filled enamel sealant with that of an unfilled non fluoride control on 177 teeth in 18 patients using split mouth design. Half treated with transbond MIP and other half treated with fluoride releasing sealant. 12 orthodontic faculty and residents evaluated decalcification on a graded scale. They concluded both products were equivalent in their inhibition of decalcification during orthodontic treatment.

Eser Tufekci, Julian S. Dixon et al [49](2011): did a study to determine the prevalence of white spot lesion in patients undergoing fixed orthodontic treatment at 6 and 12 months intervals using the visual examination method. Maxillary teeth from the right second

premolar to the left second premolar were isolated with cotton rolls and air-dried for 5 seconds. Examiners assessed the tooth surface gingival to arch wire. Upon clinical examination, teeth were given a visual score based on the extent of demineralization. They concluded that a sharp increase in the number of white spot lesions during the first 6 months (38%) of treatment that continued to rise at a slower rate to 12 months (46%). They recommended the clinician to evaluate the oral hygiene status of patients during initial month and if necessary, should implement extra measures to prevent demineralization.

Emad F. Al Maaitah, Adejumoke A. Adeyemie et al[50] (2011): determined the presence and amount of demineralization using light induced fluorescence and the effectiveness of various toothpastes at reducing demineralization during retention. Demineralized enamel showed reduction in fluorescence with respect to surrounding sound enamel. Patients with inadequate pretreatment oral hygiene developed more white spot lesions. Patients with diseased first molars had significantly greater demineralization. They concluded that sex, pretreatment age, oral hygiene, and clinical status of the first molars can be used as predictors for development and severity of white spot lesions during orthodontic treatment.

Michael A. Robertson, Chung How Kau et al [51](2011): determined the effectiveness of MI Paste Plus on the formation and resolution of white spot lesions in sixty patients undergoing orthodontic

treatment. The paste was delivered in a prefabricated fluoride varnish tray and used once daily for 3 months. Photographic records were obtained and enamel decalcification index was used to record presence or absence of white spot lesions. Results showed that the MI paste plus helped to prevent the development of new white spot lesions during orthodontic treatment and decreased the number of lesions already present. The placebo paste had no preventive action on WSLs, MI paste reduced the white spots on gingival surface but the placebo paste had the opposite effect and the incisal surface effect on mean enamel decalcification index scores over time and between products was highly significant.

Roslyn J. Mayne et al[52](2011) conducted a study and determined that effect of remineralizing WSL with a 1% (w/v) casein phosphopeptide amorphous calcium fluoride phosphate (CPP-ACP) solution reduced iatrogenic enamel damage before bracket and adhesive removal.

Blake J. Mafield, Ahmad M. Hamdan et al[53] (2012) assessed the perceptions and level of awareness of patients, parents, orthodontists, and general dentists towards the development of white spot lesions during orthodontic treatment. An epidemiological survey was done to assess the perception. Results showed that all group had similar perceptions regarding the significance, prevention, and treatment of white spot lesions. They also indicated that patients were more responsible for the prevention of white spot

lesions. Communication among all groups is needed to improve to decrease the incidence of white spot lesions in orthodontic population.

Alessandra Lucchese, Enrico Gherlone et al[54] (2012) did a cross section study on 191 patient to determine the prevalence of white spot lesions in patients with fixed orthodontic appliances Lesions were evaluated by visual examination using the scoring system proposed by Gorelick. Results showed that no significant difference was observed between groups treated 6 months and 12 months. There were more white spot lesions in group I than in group II. No significant difference was found between boys and girls. Study revealed significant decalcification at 6 months after orthodontic bonding so early diagnosis is of critical importance.

Mehmet Akin et al [55] (2012) compare the effects of sodium fluoride mouth rinse, casein phosphopeptide-amorphous calcium phosphate (CPP-ACP), and the microabrasion technique in treating the white spot lesions among 80 patients and concluded that use of CPP-ACP can be more beneficial than fluoride rinse for postorthodontic remineralization.

Michael Knosel et al [56](2012): did a study to identify the susceptibility of iatrogenic white spot lesion formation after inattentive, surplus orthodontic etching with 30% phosphoric acid for either 15 0r 30 seconds with and without careful enamel brushing on the formation of cariogenic white spot lesions in a

period of 6 weeks after etching and bonding. The result showed that factors of enamel brushing, trial time elapse, and etching had a comparably significant effect on lesion progression. They concluded that excessive surplus orthodontic etching of the complete labial enamel surface, instead of bracket basis only, must be avoided to prevent iatrogenic white spot lesions. Etching times not exceeding 15 seconds are favorable.

Greg J. Huang et al [57](2013):did a randomized control trial to assess the effectiveness of two agents commonly used to ameliorate white spot lesions compared with a normal home care regimen. The study concluded that MI Paste Plus and Prevident fluoride varnish do not appear to be more effective. The normal home care regimen found to improve the appearance of white spot lesions over an eight week period.

Lauren Manfred, David A. Covell et al [58](2013) did a study to compare the bioactive glass incorporated resin with traditional resin in preventing white spot lesion and to evaluate the ability of BAG-bonds to inhibit superficial enamel demineralization surrounding orthodontic brackets after being exposed to an in vitro caries 50 extracted were etched with 37% phosphoric acid gel for 30 seconds and rinsed with water. Orthodontic brackets are bonded on these teeth using one of four novel bioactive glass (BAG)-containing orthodontic bonding agents or commercially available Transbond XD. Teeth were cycled through low pH demineralizing and

physiologic pH remineralizing solutions once each day over 14 days. KnoopMicro hardness was measured on teeth 100, 200, 300 um from bracket base and 25 to 250 um from enamel surface. The results showed that BAG-Bond adhesives outperformed Transbond XT at maintaining superficial enamel hardness surrounding orthodontic brackets. Combining ideal bioactive glass into resin adhesive reduces enamel softening surrounding orthodontic brackets compared to a conventional resin adhesive.

Katie C. Julien, Peter H. Buschang et al[59] (2013): did a study to quantify the prevalence of visible white spot lesions on anterior teeth and to evaluate risk factors and predictors. The study included 885 patients and evaluated six anterior maxillary teeth and mandibular teeth. Digital photographs of randomly chosen patients were evaluated before and after treatment. Flurosis was evaluated based on the initial photographs due to composite removal and subsequent enamel desiccation in the post treatment photographs. Only fluorosis on the anterior teeth was considered. The results showed that nearly 25% of the patients developed white spot lesion while in treatment, depending on fluorosis, treatment time, preexisting and oral hygiene. There were more lesions in the maxillary arch than the mandibular arch. There was no gender difference, but males had a slightly higher risk.

Cochrane et al [60] (2013) analysed the fluoride, calcium and inorganic phosphate ion release among MI Varnish, Clinpro White,

Enamel Pro, Bifluorid 5 and Duraphat by ion chromatography and expressed them as lmol (cumulative) per gram of varnish and found MI Varnish containing CPP-ACP had the highest release of calcium and fluoride ions.

Hussan Milly, Frederic Festy et al[61] (2014)did an in vitro study to evaluate the potential of bio-active glass(BAG) powder and BAG containing poly acrylic acid(PAA-BAG) to remineralize enamel white spot. Lesions were created using 8% methylcellulose gel buffered with lactic acid layer. For 14 days at 37 C. teeth with artificial lesion were assigned to 4 experimental groups (a) BAG slurry, (b) PAA-BAG slurry, (c) Standard remineralization solution and (d) de-ionized water. Raman spectroscopy was used to scan lesion cross section. Another 20 samples were used to assess the sound enamel reference level and it was scanned using scanning electron microscopy. The results showed that BAG and PAA-BAG surface treatments enhance white spot lesion remineralization assessed by the resultant improved mechanical properties, higher phosphate contents and morphological changes within the artificial lesions. Smaller particle precipitations were detected within PAA-BAG compared to the BAG, this has a potential to promote entire mineral gain of treated lesions.

Pithon et al [62](2015) evaluated the efficiency of applying varnish containing casein phosphopeptide(CPP) and amorphous calcium phosphate (ACP) in prevention of caries lesion around orthodontic

brackets, on vestibular surface of bovine incisors. They found that MI Varnish was more effective in diminishing caries lesion depth, compared with Duraphat, irrespective of being associated with brushing and mouth wash, or not and CPP–ACP-containing reduced depth of caries lesions around orthodontic brackets.

Damian Hochli, Monika Hersberger-Zurfluh et al [63](2016): did a systematic review and meta analysis to critically assess the evidence from randomized clinical trials on humans investigating interventions to treat WSLs that originated from fixed orthodontic therapy. They included parallel study or split-mouth RCTs on human patients comparing any intervention. An unrestricted electronic search of eight databases was done and they selected only randomized control trials. The risk of bias was assessed by Cochrane's risk of bias tool. They concluded based on existing trials that interventions for post-orthodontic white spot lesion mainly fluoride varnish or 5 % sodium fluoride film seem to be effective than daily tooth brushing with a fluoride dentifrice. But research is needed to elucidate their clinical relevance.

Federico Perrini, Luca Lombardo et al[74](2016): did an in vivo study to evaluate the efficacy of Duraphat a fluoride varnish in preventing white spot onset over a longer period, 12 months, in patients with fixed appliances with the help of laser fluorescence. Study concluded that there was no statistically significant difference in the demineralization between treated and untreated

teeth. The periodic application of fluoride varnish can offer some protection against white spots, but not to a significant degree in the course of time.

MATERIALS AND METHODS

Materials & Methodology:

Materials:

- MI varnish
- Fluoritop
- Applicator tip
- Thymol
- Normal saline / Transport media
- Transferring sterile plastic bottle
- Microtip pencil (0.5mm)
- Vickers Microhardness tester

Methodology:

Total subjects: 30

Subject selection criteria:

Patients who reported to the Department of orthodontics, Adhiparasakthi Dental College & Hospital (APDC &H), who fulfilled the following criteria were recruited for the study.

Inclusion criteria

- Age range of 15-25 years.
- Both the genders.
- Full compliment of permanent dentition excluding third molars.

- Angle`s Class I malocclusion with bimaxillary protrusion (ANB of 0 to 2 Degree).
- Cases requiring extraction of both the maxillary and mandibular first premolars.
- No previous history of extraction or fixed orthodontic treatment.

Exclusion criteria:

- Attrition, Abrasion, Erosion, Enamel Hypoplasia, Enamel fracture in first premolars.
- Patient who had the habit of Smoking.
- Nickel allergy.
- Suspected allergy to milk protein.
- Subjects with systemic illness, growth abnormality & bleeding disorders.
- Subjects with history of any trauma or injury to the face.

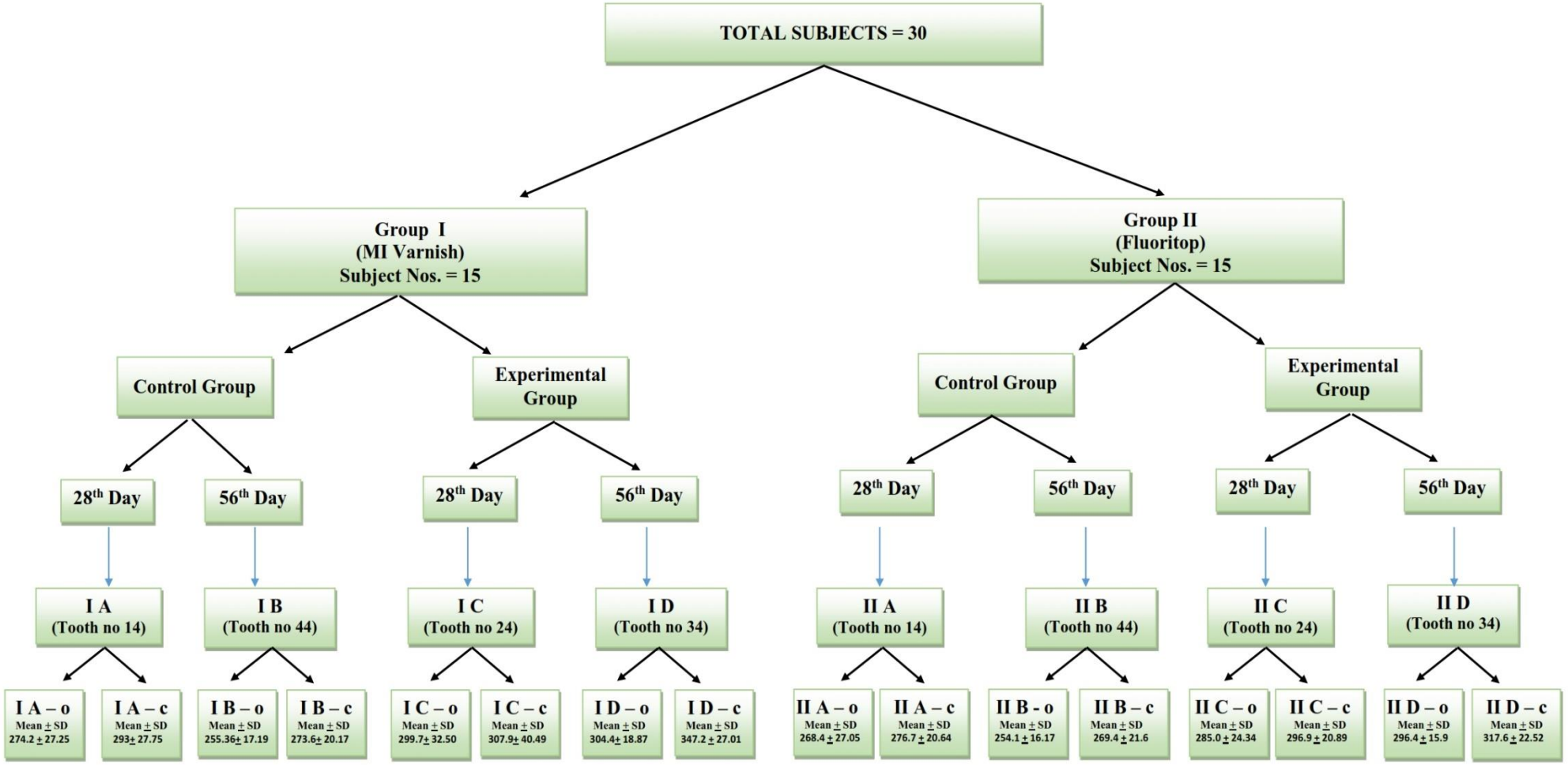
Ethical clearance:

The study design and protocol was approved by the ethical committee of Adhiparasakthi Dental College & Hospital, Melmaruvathur. The subjects were explained about the purpose of the study and an informed consent was obtained from them. In the event of the subjects being less than 19 years of age, informed consent was also obtained from the respective parents. Subjects were clinically examined before the study.

Methodology :

- 30 patients who reported to the Department of orthodontics, APDC&H, with Angle`s Class I malocclusion with bimaxillary protrusion who satisfied the inclusion criteria were selected for the study.
- 30 patients were divided into 2 groups I & II of 15 patients in each group
- Group I, consisted of 15 patients who were bonded with the fixed appliance(MBT standard 0.022 slot bracket). Tooth 14(IA) &44 (IB) were taken as control group and tooth 24(IC) & 34 (ID) were taken as experimental group. MI Varnish [GC America, USA (Fig: 1)] was coated by applicator tip around 24 & 34 tooth brackets on the day of bonding itself. (Flow Chart)
- Group II, consisted of 15 patients who were bonded with the fixed appliance(MBT standard 0.022 slot bracket). Tooth 14(IA) and 44(IB) were taken as control group and tooth 24(IC) and 34 (ID) were taken as experimental group. Fluoritop varnish [ICPA health products ltd, India (Fig: 2)] was coated by applicator tip around 24 & 34 tooth brackets on the day of bonding itself. (Flow Chart)

FLOW CHART (Sample Stratification)



- Initial 0.016″ NiTi archwire was secured in both the upper and lower arches with elastomeric modules in all the subjects.
- Patients were given following oral hygiene instructions –
  - Advised not to brush or floss teeth for atleast 4 hours.
  - To avoid hard ,hot, sticky foods and products which contained alcohol and fluoride (oral rinses and beverages).
- All the patients were recalled on 28th day after bonding.
- On the 28th day, teeth 14(IA),24(IC) and 14(IIA),24(IIC) from group I and group II respectively were extracted, cleaned with thymol and then sent to (METMECH ENGINEERS) laboratory in tranfer media in sterile plastic containers (Fig:3) for evaluation of enamel Surface Micro hardness(SMH). Tranfer media used was normal saline.
- All the patients were given next appointment after 28th day of the present appointment i.e 56th day after bonding.
- On 56th day, teeth 34(ID),44(IB) and 34(IID),44(IIB) were extracted from group I & group II respectively, cleaned with thymol and then sent to laboratory in normal saline for evaluation of enamel surface Micro hardness (SMH).

The Surface Micro hardness (SMH) of the 120 samples were measured using a Vickers micro hardness Tester [HDNS KELLY INSTRUMENTS MVD 402 SHANGHAI, Fig:4]with a load Of 200 gms for 10 seconds. All readings were performed by the same examiner using the same calibrated machine. Long axis of the tooth connecting

Zenith of gingiva and buccal occlusal tip was marked with the microtip pencil (0.05 mm) for all the sample For each sample,2 indentations were marked 2mm away from bracket surface, one occlusally and another one cervically along the long axis of the tooth. SMH was measured at these 2 indentation marks (Fig :5) with the tester in Vickers Hardness Number (VHN) units.

Fig : 1

Fig : 2

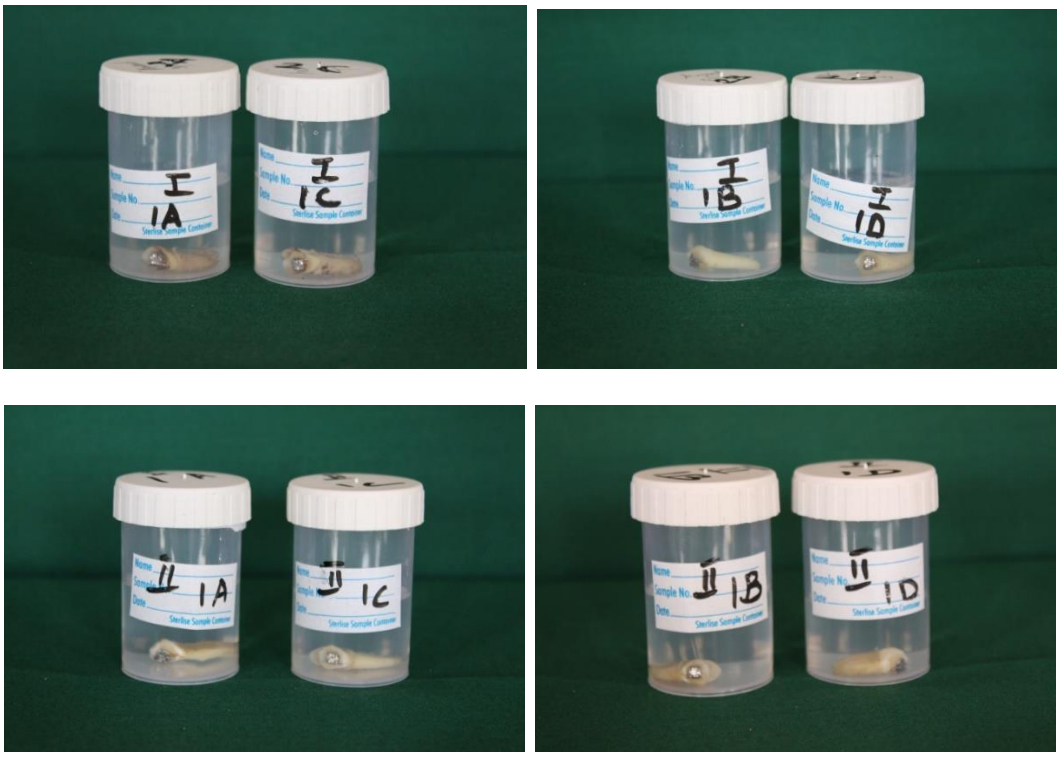
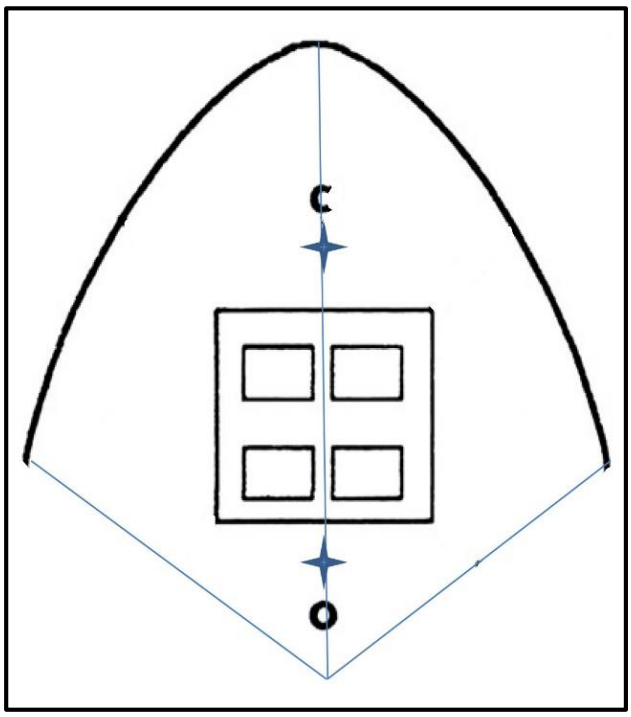


Fig: 3

Fig. 4



O- Occlusal

C- Cervical

Fig: 5

RESULT

Statistical analysis:

Statistical analysis was performed for all the samples using IBM®SPSS software version 21. The normality of the data was confirmed using Shapiro-Wilk test. Paired sample t test was performed for intragroup comparison whereas for intergroup comparison unpaired t test was performed. P value less than 0.05(< .05) was considered statistically significant.

Table 1: Descriptive statistics for Group I (MI varnish)

Site	N	Minimum	Maximum	Mean	Standard Deviation
I A - o	15	222.30	311.30	274.3067	27.25966
I A - c	15	241.90	355.50	293.0333	27.75998
I C - o	15	230.80	354.70	299.7600	32.50580
I C - c	15	245.80	371.30	307.9200	40.49244
I B - o	15	218.90	279.20	255.3600	17.19704
I B - c	15	229.40	294.70	273.6533	20.17420
I D - o	15	279.10	343.80	304.4267	18.87581
I D - c	15	302.70	382.70	347.2000	27.01457

Table 2: Comparison between Study group and Control group (MIvarnish)

	Site	N	Mean	Standard deviation	P value
Pair 1	I A -o	15	274.3067	27.25966	0.008
	I C-o	15	299.7600	32.50580	
Pair 2	I A-c	15	293.0333	27.75998	0.21
	I C-c	15	307.9200	40.49244	
Pair 3	I B-o	15	255.3600	17.19704	<0.001
	I D-o	15	304.4267	18.87581	
Pair 4	I B-c	15	273.6533	20.17420	<0.001
	I D-c	15	347.2000	27.01457	
Pair 5	I C-o	15	299.7600	32.50580	0.590
	I D-o	15	304.4267	18.87581	
Pair 6	I C-c	15	307.9200	40.49244	0.001
	I D-c	15	347.2000	27.01457	

Table 1 description

Mean distribution of the SMH of group I (MI varnish) on 28th day in sample A at the occlusal region (I A –o) was 274.30 VHN with the standard deviation of 27.25 whereas at the cervical region (I A –c) was 293.03 VHN with the standard deviation of 27.75

Mean distribution of the SMH on 28th day in sample C at the occlusal region(IC-o) was 299.76 VHN with the standard deviation

of 32.50 whereas at the cervical region (I C-c) was 307.92 VHN with the standard deviation of 40.49.

Mean distribution of the SMH on 56thday in sample B at the occlusal region (I B-o) was 255.36 VHN with the standard deviation of 17.19 whereas at the cervical region (I B-c) was 273.65 VHN with the standard deviation of 20.17.

Mean distribution of the SMH on 56th day in sample D at the occlusal region (I D-o) was 304.42 VHN with the standard deviation of 18.87 whereas at the cervical region (I D-c) was 347.20 VHN with the standard deviation of 27.01

Table 2 description

The results obtained after comparing sample A and sample C of group I SMH at the occlusal region (I A –o and IC-o) was found to be 274.30 VHN and 299.76 VHN respectively which was found **statistically significant (P= 0.008)** whereas at the cervical region(I A –c and IC-c) it was 293.03 VHN and 307.92 VHN respectively which was not statistically significant (p=0.21)

The results obtained after comparing sample B and sample D of group I SMH at the occlusal region (I B-o and ID-o) was found to be 255.36 VHN and 304.42 VHN respectively which was **statistically significant (P<0.001)** whereas at the cervical region (I B-c and ID-c)it was 273.65 VHN and 347.20 VHN respectively which was **statistically significant (P<0.001)**

The results obtained after comparing sample C and sample D of group I the SMH at the occlusal region (I C-o and ID-o) was found to be 299.76 VHN and 304.42 VHN respectively which was not statistically significant (P=0.59) whereas at the cervical region(I C-c and ID-c) it was 307.92 VHN and 347.20 VHN respectively which was **statistically significant (P<0.001)**

Table 3: Descriptive Statistics for group II (Fluoritop)

	N	Minimum	Maximum	Mean	Std. Deviation
II A-o	15	215.30	305.30	268.4400	27.05359
II A-c	15	235.90	311.80	276.7000	20.64202
II C-o	15	233.80	314.70	285.0267	24.34723
II C-c	15	247.80	327.10	296.9867	20.89022
II B-o	15	211.90	275.20	254.1600	16.71718
II B-c	15	221.40	295.30	269.4533	21.64172
II D-o	15	269.60	321.30	296.4933	15.95581
II D-c	15	291.30	359.60	317.6667	22.52705

Table 4: Comparison between Study group and control group (Fluoritop)

Site		Mean	N	Standard Deviation	p value
Pair 1	II A-o	268.4400	15	27.05359	0.001
	II C-o	285.0267	15	24.34723	
Pair 2	II A-c	276.7000	15	20.64202	0.001
	II C-c	296.9867	15	20.89022	
Pair 3	II B-o	254.1600	15	16.71718	0.001
	II D-o	296.4933	15	15.95581	
Pair 4	II B-c	269.4533	15	21.64172	0.001
	II D-c	317.6667	15	22.52705	
Pair 5	II C-o	285.0267	15	24.34723	0.070
	II D-o	296.4933	15	15.95581	
Pair 6	II C-c	296.9867	15	20.89022	0.001
	II D-c	317.6667	15	22.52705	

Table 3 description

Mean distribution of the SMH of group II (Fluoritop) on 28th day in sample A at the occlusal region (II A-o) was 268.44 VHN with the standard deviation of 27.05 whereas at the cervical region(II A-c) was 276.70VHN with the standard deviation of 20.64.

Mean distribution of the SMH on 28th day in sample C at the occlusal region (II C-o) was 285.02 VHN with the standard deviation of 24.34 whereas at the cervical region (II C-c) was 296.98 VHN with the standard deviation of 20.89.

Mean distribution of SMH on 56th day in sample B at the occlusal region (II B-o) was 254.16 VHN with the standard deviation of 16.71 whereas at the cervical region (II B-c) was 269.45VHN with the standard deviation of 21.64.

Mean distribution of the SMH on 56th day in sample D at the occlusal region (II D-o) was 296.49 VHN with the standard deviation of 15.95 whereas at the cervical region (II D-c) was 317.66 VHN with the standard deviation of 22.52

Table 4 description

The results obtained after comparing sample A and sample C of group II the SMH at the occlusal region (II A-o and IIC-o) was found to be 268.44 VHN and 285.02 VHN respectively which was **statistically significant (P<0.001)** whereas at the cervical region(II A-c and IIC-c) it was 276.70 VHN and 296.49VHN respectively which was **statistically significant** (**p<0.001**)

The results obtained after comparing sample B and sample D of group II the SMH at the occlusal region (II B-o and IID-o) was found to be 254.16 VHN and 296.49VHN respectively which was **statistically significant (P<0.001)** whereas at the cervical region

(II B-c and IID-c) was 269.45 VHN and 317.66 VHN respectively which was **statistically significant (P<0.001)**

The results obtained after comparing sample C and sample D of group II the SMH at the occlusal region (II C-o and IID-o) was found to be 285.02 VHN and 296.49 VHN respectively which was not statistically significant(p=0.07) whereas at the cervical region (II C0-c and IID-c) it was 296.98 VHN and 317.66 VHN respectively which was **statistically significant (P<0.001)**

Table 5: Intergroup comparison between group I (MI varnish) and group II (Fluoritop)

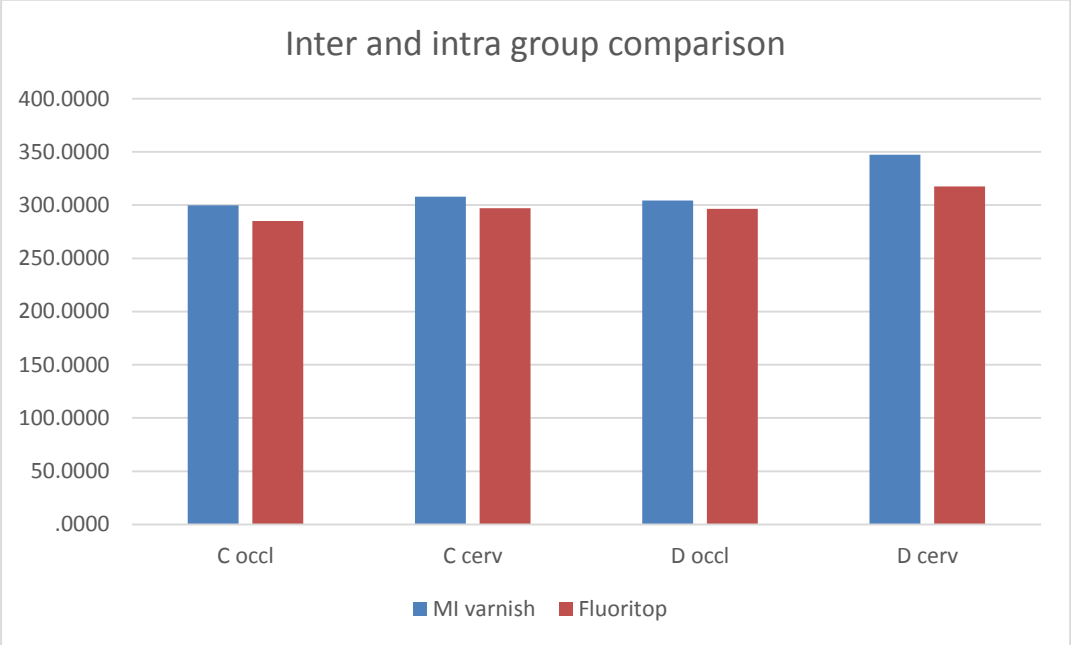
	Groups	N	Mean	Std. Deviation	Mean diff	p value
C occl	I C-o	15	299.7600	32.50580	14.73333	.171
	II C-o	15	285.0267	24.34723		
C cerv	I C-c	15	307.9200	40.49244	10.93333	.361
	II C-c	15	296.9867	20.89022		
D occl	I D-o	15	304.4267	18.87581	7.93333	.224
	II D-o	15	296.4933	15.95581		
D cerv	I D-c	15	347.2000	27.01457	29.53333	.003
	II D-c	15	317.6667	22.52705		

Table 5 description

The results obtained after comparing group I and group II SMH at the occlusal region (IC-o and IIC-o) on 28th day was found

to be 299.76 VHN and 285.02 VHN respectively which has no statistically significance (p=0.17) and at the cervical region (IC-c and IIC-c) it was 307.92 VHN and 296.98 VHN respectively which also has no statistically significance (P=0.36)

The results obtained after comparing group I and group II SMH at the occlusal region(ID-o and IID-o) at 56th day was found to be 304.42VHN and 296.49 VHN respectively which has no statistically significance (p=0.22)and at the cervical region (ID-c and IID-c) it was 347.20 VHN and 317.66VHN respectively which was **statistically significant (P< 0.003)**



DISCUSSION

The tooth enamel structure is an unique one which has no residual cellular components to repair when it gets damaged by a cariogenic episode. Demineralization and remineralization (repair or healing) of enamel are continous and constant processes occurring on the availability of acidogenic bacterial flora on the plaque biofilm and refined carbohydrates. The plaque biofilm facilitates the attachment and spread of acidogenic bacteria resulting in WSLs formation. The plaque biofilm can harbor more concentrations of fluoride, calcium, and phosphate complexes. The plaque biofilm encloses numerous microenvironments that can be disrupted through chemomechanical systems such as applications of topical fluoride, CCP–ACP, and tooth brushing. Reduced enamel subsurface demineralization was found when enamel plaque is exposed to solutions of trypticpeptides of casein. Thus, incorporating casein peptides into enamel plaque increases the plaque content of calcium and phosphate[64]. Farhadian et al [65] concluded that one topical application of fluoride varnish in high concentration can decrease enamel lesion depth adjacent to bonded brackets upto 40% for 3 months.

CCP–ACP acts as a reservoir of calcium and phosphate. These minerals form nanocomplexes in the biofilm and on the tooth surface, creating a barrier that is highly resistant to changes in pH arising from acidogenic environment.

The active CPP is capable of binding to calcium and phosphates of enamel and also stabilizes ACP simultaneously. Reduced pH in the plaque result in calcium and phosphate ions release from CPP resulting in supersaturation which reduces demineralization and promotes remineralization of enamel by binding to enamel calcium and phosphates[66,67]. With this in mind, this study was conducted to compare the effectiveness of CPP–ACP varnish (MI varnish) and sodium fluoride varnish (fluoritop varnish) in preventing formation of WSLs and promoting remineralization of the lesion. In our study, an increased demineralisation was found at occlusal region compared to the cervical region of the tooth in general. This inference was held true for both the control and experimental groups as shown in table 2 and 4 .Our results were in contrast to the study by Pascotto et al[68] where they observed reduced enamel hardness in the cervical region of the bracket compared with that in the occlusal area. In vivo, the explanation for this observation was greater dental plaque accumulation and difficulty in cleaning the area. Explanation for this variation of results in our study could be the variation found in the enamel SMH at the occlusal and cervical region of the tooth. A pilot study was conducted to evaluate the hypothesis whether there is variation in SMH at different region of the tooth and it was found that enamel hardness was maximum at middle third followed by occlusal 3rd and then the minimum at cervical 3rd of the tooth. Table 2 and 4 showed that the loss of enamel substance was found to be reduced by the

topical application of both MI varnish and Fluoritop in the experimental group when compared to control group at the end of 28th day after bonding .This reduced demineralisation was found to be statistically significant for both MI group and Fluoritop group except occlusal region of MI varnish group. There was no statistical significance found when the effectiveness of both MI varnish and Fluoritop in reducing demineralisation was compared at the end of 28th day of bonding.

At the end of 56th day after bonding also, the demineralisation was reduced in both the groups which was found to be statistically significant as shown in table 2 and 4.

By comparing the results obtained at 28th day and 56th day, it was also noticed that there was not only decrease in demineralisation but also there was remineralisation of the WSLs especially in the cervical region which was statistically significant in both MI varnish and fluoritop groups as shown by pair 6 of table 2 and 4 respectively. With this, a time dependent remineralisation could also be concluded. Finally no statistical significant difference was found between MI varnish and Fluoritop in preventing WSLs except in cervical region where MI varnish was found to be statistically significant compared to Fluoritop.

The results of this study agree with several other clinical trials .A study by Kumar et al[69] indicated that CPP-ACP containing Tooth Mousse remineralized initial enamel lesions and showed a

higher remineralizing potential when applied as a topical coating after the use of fluoridated toothpaste. A study by Giulio et al stated that topical applications of Tooth Mousse, could be effective in promoting enamel remineralization after interdental stripping [70]. In Ferreira et al study fluoride contained in the dentifrices used for oral hygiene was capable of potentiating the protection of enamel in the demineralization process when used in conjugation with the use of fluoridated varnish. A study by pithon et al[62] Ml varnish used without any other oral hygiene procedure would be capable of significantly reducing the depth of carious lesions whereas Duraphat varnish (5 % sodium fluoride varnish) was effective only when it was supported with brushing and fluoridated mouth wash. In an another study by Robertson[52] MI Paste Plus not only prevents WSLs development during orthodontic treatment, but also reduces the number of white spots already present, with greater impact on the gingival surfaces.

In contrast to our results, several randomized clinical trials were reported by Greg J. Huang et al where they compared the effectiveness of MI Paste Plus and PreviDent fluoride varnish (22,600 ppm of fluoride) with a standard oral hygiene regimen with toothpaste containing 1100 ppm of fluoride in patients who debonded their orthodontic appliances within the period of 2months and had at least 1 white spot lesion affected their maxillary incisors by assessing before and after photographs. MI Paste Plus and PreviDent fluoride varnish were not more effective when compared

to normal home care for improving the appearance of white spot lesions over an period of 8 weeks[71].Another contradictory study by Beerens MW et al showed that there were no significant differences between CPP-ACFP paste (MI Paste Plus) and the fluoride-free control paste on the remineralization of enamel WSLs and plaque composition during a 3-month follow- up. In both groups, limited changes in fluorescence loss were found 12 wk after debonding, but a decrease in the percentage of aciduric bacteria and S. mutans in the plaque was detected over time[72.] Another randomized trial compared WSLs treated with a low-fluoride mouth rinse (50 ppm) to those treated with a nonfluoride mouth rinse. At 12 weeks, the lesions had decreased by 40% (SD, 14.5) in the treatment group and by 51.5% (SD, 12.3) in the control group, indicating no significant benefit from the low-level fluoride[14]. Explanation to all above contrary studies could be the retention period or duration of their product used around the brackets. In above studies, they used products in paste or rinse form which would not have longer retention around the bracket. On the contrary to this, in our study we used product in varnish form which showed minimum of 3 months to 6 months retention period around the brackets (Farhadian et al[65]). We might have got statistical significance in effectiveness of varnish in preventing WSL because of this retentivity property of varnish.

In Ann Bröchner et al[73] study 60 adolescents patients with at least one clinically visible labial white spot lesion within the enamel at the time of debonding of fixed orthodontic appliances to check the efficacy of 10% casein phosphopeptide–amorphous calcium phosphate (CPP–ACP) on wsl over a period of 4 weeks, assessed by quantitative laser fluorescence and visual scoring (Gorelick scale) from digital photographs. In this study the lesions decreased by 26% to 58%, but no significant differences were found between the casein phosphopeptide amorphous calcium phosphate and the control groups.

LIMITATIONS OF THE STUDY

Split mouth technique will have carry-across effect due to fluoride or calcium and phosphate release by the agents on enamel around the brackets. Patient compliance was not monitored and factored into the process. The most effective means of studying decalcification is to carry out a histosection of the enamel of the teeth which was not used for our study.

In the future, patient's compliance should also be taken into consideration. Microhardness of both cervical and occlusal region of tooth should be first evaluated separately for all upper and lower 1st premolars before the start of the study for standardization. In the future orthodontic bonding adhesives containing casein phosphopeptide-amorphous calcium phosphate could become popular. At present, the American Dental Association Foundation is

developing biologically remineralizing composites, or “smart composites,” that contain amorphous calcium phosphate. Even sports drinks are being developed that contain casein phosphopeptide-amorphous calcium phosphate. The possibilities for its applications are endless.

SUMMARY AND CONCLUSION

- Our study concluded that generalized demineralization occurs around the bracket surfaces of teeth in patients undergoing orthodontic treatment.

- There was significant decrease in demineralisation and increase in remineralization found by topical application of MI varnish as well as Fluoritop at 4^{th} and 8^{th} week intervals around the bonded tooth.

- There is no statistical significance found in relation to in vivo effectiveness comparison of MI varnish and fluoritop except in cervical region .where MI varnish was found to be more effective than fluoritop in preventing WSLs.

- Time dependent remineralization could be concluded.

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PARTICIPANT INFORMED CONSENT FORM (PICF)

(English)

Protocol / Study number: _____

Participant identification number for this trial: _____

The contents of the information sheet dated that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from APDCH. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

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(Signatures / Left Thumb Impression) Signatures of the Principal Investigator

<u>ஆராய்ச்சியில் பங்கேற்பதற்கு இணக்கம்</u>

தேதி:

நோயாளியின் பெயர் :

வயது / பாலினம் :

புறநோயாளி எண் :

அறுவை சிகிச்சை மருத்துவ நிபுணரின் பெயர் :

சிகிச்சையின் பெயர் :_____

அளிக்கப்படும் மயக்க மருந்தின் வகை :

எனது தற்போதைய வாய்நலம் குறித்தும், அதற்கு உரிய சிகிச்சை முறைகளையும், மாற்று சிகிச்சை முறைகளையும் மற்றும் சிகிச்சை மேற்கொள்ளாவிடில் ஏற்படும் பின்விளைவுகளையும் பல் மருத்துவர் முழுமையாக என்னிடம் கூறினார். அதற்கான எனது சந்தேகங்களையும் பல் மருத்துவரிடம் கேட்டு தெளிவுபடுத்திகொண்டேன். மேலும் சிகிச்சை முறை, என் சிகிச்சையின் போது தேவைப்படும் மயக்கமருந்துகள் மற்றும் பிறமருந்துகள் செலுத்த சம்மதிக்கின்றேன். நான் மனப்பூர்வமாக எனது சிகிச்சை முறை மற்றும் அதனால் வரும் பின் விளைவுகளையும் ஏற்றுக் கொள்கிறேன் மற்றும் மருத்துவர் கூறும் அறிவுரைகளையும் கடைபிடிப்பேன்.

மேலே சொல்லப்பட்டு இருக்கும் ஆராய்ச்சி ஆய்வில் பங்கேற்பதற்கு மனப்பூர்வமான எனது சம்மதம்.

மேலுள்ள தகவல்கள் உள்ளிட்டு ஆராய்ச்சி ஆய்வானது வாய்வழியாக விளக்கப்பட்டிருக்கிறது மற்றும் பங்கேற்பதற்கு சுயவிருப்பத்தில் இணங்குகிறேன் என்பது இந்த ஆவணத்தில் கையெழுத்திடுவதன் அர்த்தமாகும்.

நோயாளியின் கையொப்பம் அறுவை சிகிச்சை நிபுணரின் கையொப்பம்

PLAGIARISM CERTIFICATE – II

This is to certify that this dissertation work titled **"EVALUATION OF EFFECTIVENESS OF VARNISH CONTAINING FLUORIDE AND FLUORIDE VARNISH WITH CPP-ACP IN PREVENTION OF WHITE SPOT LESIONS IN PATIENTS UNDERGOING FIXED ORTHODONTIC THERAPY - AN INVIVO COMPARATIVE STUDY"** of the candidate **Dr N.KARIKALAN** with registration Number **241519451** for the award of Master of Dental Surgery in the branch of Orthodontics and Dentofacial Orthopedics. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 7% percentage of plagiarism in the dissertation.

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This ethical committee has undergone the research protocol submitted by **N.KARIKALAN**_Post Graduate Student, Orthodontics and Dentofacial Orthopedics under the title **"EVALUATION OF EFFECTIVENESS OF VARNISH CONTAINING FLUORIDE AND FLUORIDE VARNISH WITH CPP-ACP IN PREVENTION OF WHITE SPOT LESIONS IN PATIENTS UNDERGOING FIXED ORTHODONTIC THERAPY - AN INVIVO COMPARATIVE STUDY",** Reference No: **2015-MD-Br II-MAN-12/APDCH** under the guidance of **DR. V.SUDHAKAR** for consideration of approval to proceed with the study.

This committee has discussed about the material being involved with the study, the qualification of the investigator, the present norms and recommendation from the Clinical Research scientific body and comes to a conclusion that this research protocol fulfils the specific requirements and the committee authorizes the proposal.

Date:

CHAIR PERSON

- Inform IEC/IRB immediately in case of any issue(s) / adverse events.
- Inform IEC/IRB in case of any change of study procedure, site and investigator.
- Annual report to be submitted to IEC/IRB.
- Members of IEC/IRB have right to monitor the trial with prior intimation.